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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,371	01/07/2002	Jon Bragi Bjarnason	P 284960 176US1-DIV	5545

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EXAMINER	
PATTEN, PATRICIA A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,371	BJARNASON, JON BRAGI	
	Examiner	Art Unit	
	Patricia Leith	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-31 and 40-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-31, 43-45 and 48--50* is/are rejected.

7)☒ Claim(s) *40-42,46 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-31 and 40-50 are pending in the application and were examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 43 and 48 are drawn to wherein the trypsin has 'at least 90% amino acid sequence homology with any of trypsin I, trypsin II, trypsin III derived from Atlantic cod'.

Applicant's arguments were fully considered, but not found convincing.

Applicants argue that 'Trypsin sequences from various species are very well known' (p.4- Arguments). Applicants contend that because these types of sequences are known, as indicated by Leiros et al. for example, as well as the fact that isoforms of cod trypsin are polymorphic, that the skilled artisan would not need to perform undue experimentation to make and use the claimed invention.

However, Applicants are claiming a method for using the trypsin for performing a particular function; treatment of disorders such as arthritis and eczema. The Examiner concedes that trypsin sequences are known, however, what has not been disclosed in the Instant specification is the sequence which is actually beneficial for treating the claimed diseases. Therefore, no nexus has been established between a *particular* sequence of amino acids and treatment of arthritis for example.

It is clear from the Instant specification that Atlantic cod trypsin has some effect on the Instantly claimed diseases, however, Applicants have not provided an exact sequence of amino acids which would perform these functions. What 10% of the amino acid sequence of Trypsin I, II or III from Atlantic cod can be rearranged in order to form an Atlantic cod trypsin which performs equivalently to the Atlantic cod trypsin as demonstrated in the Instant specification? This question cannot be answered because of the lack of guidance present in the Instant specification. Therefore, the skilled artisan would need to perform undue experimentation in order to ascertain what sequences, which are 90% homologous to the Atlantic cod trypsin, would actually work

commensurate in scope with the claimed invention. This experimentation would be undue considering the expensive trial and error protocols which would need to be performed in order to verify the effectiveness of every amino acid sequence which was 90% homologous to trypsin derived from Atlantic cod.

The response seems to argue that 35 U.S.C. ' 112, first paragraph, permits an artisan to present claims of essentially limitless breadth so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. This argument is not entirely without merit. However, the issue here is the *breadth of the claims in light of the predictability of the art* as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

It is noted that there is not a single example in the instant specification, working or prophetic, of any trypsin protein whose amino acid sequence deviates from the Atlantic cod trypsin amino acid sequence. Since there are **no** working examples, then one must consider the guidance provided by the instant specification and the prior art of

record. The instant specification provides absolutely no guidance as to which amino acid residues of Atlantic cod trypsin are essential for the functional and structural integrity of the Atlantic cod trypsin and which residues are either substitutable or expendable. Further, there is no functionally and structurally analogous protein which has been identified in the prior art for which this information is known and could be extrapolated to trypsin by analogy. In conclusion, the instant claims encompasses a vast, almost limitless, number of proteins having non-naturally occurring amino acid sequences and yet the instant specification provides no working examples and no guidance that would permit and artisan to practice the invention commensurate with the scope of the instant claims.

Accordingly, in the present instance, the claimed invention encompasses a veritable plethora of possible proteins of diverse structure and type and the use thereof as a pharmaceutical for treating conditions such as arthritis. The inadequate disclosure coupled with a lack of representative examples and the art recognized unpredictability with respect to the effects of bioactivity of making *even subtle changes* to the amino acid structure of the underlying compounds, thus preclude the making and use of compounds within the scope of the presently claimed invention by the skilled artisan without undue experimentation.

Claim Rejections - 35 USC § 103

Claims 28-31, 44-45 and 48--50 remain rejected over Faire et al. (US 5,958,406).

Applicants' arguments were fully considered, but not found convincing.

Applicants argue that the cod derived trypsin and chymotrypsin have 'less than 70% homology with the krill derived multifunctional enzyme' and therefore the statement made by Dair et al. 'the enzymes.....krill enzyme' would not lead one of ordinary skill in the art to recognize that the serine proteases of [the] present invention would have the same utility as disclosed by de Faire et al because of their relatively low sequence homology. Applicants further note that the serine proteases of the Instant application have unexpected results (p. 6- Arguments).

The unexpected result with regard to Atlantic cod trypsin is duly noted as evidenced by the patentability of claims 40-42 and 46-47 (see *infra*). However, the remainder of the claims are drawn simply to 'fish serine protease' or 'trypsin' whereby *no unexpected results were observed save for the trypsin from Atlantic cod.* Subsequently, Applicants' arguments pertaining to sequence variation between the krill multifunctional enzyme and the Atlantic cod enzyme are only convincing toward claims 40-42 and 46-47 because no other unexpected results were shown for all other fish serine proteases and/or trypsins.

It is noted that the krill multifunctional enzyme does display similar utility, as evidenced by de Faire et al. because it is used for the same purpose. Because de Faire et al. clearly stated that the multifunctional enzyme can be useful for treating skin conditions such as acne or eczema as long as it has one of chymotrypsin, trypsin, collegenase or ellastase activity (claim 1, Abstract and col.3, lines 16-33) the ordinary artisan would have recognized that an enzyme displaying one of these functions would have been useful for treating skin conditions. It is clear that a multifunctional enzyme which has only one function, i.e., chymotrypsin activity, is not multifunctional. Although the krill enzyme was, in fact, a multifunctional enzyme does not limit the scope of *what was taught in de Faire et al.,* that an enzyme with any of these properties would have been efficacious.

Allowable Subject Matter

Claims 40-42 and 46-47 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0968. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Examiner
Art Unit 1654

03/16/04